UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PRISCILLA GARCIA, et al., Plaintiffs, v. CROWN LABORATORIES, INC., Defendant.	**DISCOVERY ORDER** Case No. 24-cv-01448-EMC (TSH) Re: Dkt. No. 91
LINDSEY DAUGHERTY, et al., Plaintiffs, v. PADAGIS (US) LLC, et al., Defendants.	Case No. 24-cv-02066-EMC (TSH) Re: Dkt. No. 77

Judge Chen gave Plaintiffs leave to take "written discovery designed to determine whether the cGMPs were violated in a manner that does not require interpretation or scientific/technical judgment, i.e. violations provable in a manner similar to that in *Sprout*." 24-cv-1448 ECF No. 84 at 20. The parties have filed joint discovery letter briefs in the above actions concerning those discovery requests. The requests at issue are the same in both cases.

As an initial matter, the Court rejects the *Garcia* Defendant's argument that RFPs are not a form of written discovery. Yes, they are.

All of the RFPs are legitimate attempts to take discovery to determine whether the cGMPs were violated in a manner that does not require interpretation or scientific/technical judgment. Importantly, in resolving this discovery dispute, the Court does not rule on the merits of Plaintiff's

implied theories of liability. Judge Chen will decide merits issues. A big merits issue that divides the parties is whether a cGMP has to be specific to benzene for the absence of a requirement to amount to a violation that requires no interpretation. The Court does not resolve that dispute.

For example, RFP 1 requests "All Documents referring to written procedures describing the 'storage, handling, sampling, testing, and approval or rejection' of BPO in relation to benzene as a degradant, adulterant, contaminant, or impurity, used in the manufacturing of the Products. *See* 21 CFR § 211.80(a)." The cited cGMP states: "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed." If the requested documents show that Defendants do not have any written procedures for sampling or testing of benzene, Plaintiffs would likely allege that this is a cGMP violation that does not require interpretation or judgment. By contrast, if Defendants have written procedures covering the various subjects as they pertain to benzene, but it's unclear whether the written procedures have "sufficient detail," Plaintiffs would not likely think they have found a violation that doesn't require interpretation or judgment.

Again, the Court understands that this cGMP is not specific to benzene. If Plaintiffs find what they are hoping to find in discovery, they will argue to Judge Chen that they have succeeded in identifying a cGMP violation that does not require interpretation because benzene is a Class 1 carcinogen, and Defendants will argue they have failed because the cGMP is not specific to benzene. Right now the Court is merely determining whether Plaintiffs' discovery is appropriately directed at the legal theories they intend to pursue, not whether those theories have merit.

The *Garcia* Defendant seems to argue that in order to determine whether a cGMP violation requires interpretation, all you need to do is read the cGMP. However, that is wrong. Instead, you need to know what the alleged cGMP violation is. Let's go back to the cGMP cited in RFP 1: "There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed." As noted above, if the

alleged violation is the lack of sufficient detail in the written procedures, that probably requires interpretation. But if the alleged violation is the complete nonexistence of the written procedures, that likely does not require interpretation. Every cGMP requires *something* to be done. If you don't do it very well, compliance could be a matter of interpretation. But if you don't do it *at all*, that may not require interpretation.

The bulk of the RFPs seek relevant documents in the same manner. RFP 2 seeks "All Documents referencing how the BPO used in the manufacturing of the Products was 'stored in a manner to prevent contamination' from benzene as a degradant, adulterant, contaminant, or impurity. *See* 21 CFR § 211.80(b). The cited cGMP states: "Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination." If the BPO was stored in a bath tub of benzene, Plaintiffs will say that is a violation of the cGMP that requires no interpretation, and Defendants will dispute that because the cGMP is not specific to benzene. From the Court's review, it appears that RFPs 3, 4, 5, 6, 9, 10, 11, 12 and 13 seek relevant documents for the same reasons RFPs 1 and 2 do.

RFPs 7 and 15 also seek relevant documents but do not have the benzene issue. The Court understands that for RFP 7, there is a merits dispute about whether 77 degrees Fahrenheit constitutes "heat" within the meaning of the cGMP, or whether such a determination requires interpretation or scientific judgment. That is a merits issue for Judge Chen. The requested documents are relevant for discovery purposes.

RFP 8 similarly seeks relevant documents. It seeks "All Documents relating to Your Acceptance Criteria for BPO in the Products." Unlike the RFPs discussed above, RFP 8 does not cite a specific cGMP. However, the definitions in the cGMP regulations contain a definition of acceptance criteria: "Acceptance criteria means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units)." 21 CFR § 210.3(b)(20). Presumably, if Defendants do not have any of those things, they are not in compliance with any cGMPs that use that term.

RFP 14 asks for "All Documents referencing communications between You and the FDA related to the Products and compliance with current Good Manufacturing Practices." If the requested documents contain statements by Defendants that they do not comply with certain good manufacturing practices, that could show cGMP violations that do not require interpretation.

Having discussed relevance, the Court now turns to proportionality. The RFPs are all phrased in terms of "all documents" (or "all reports" for RFP 4), and that seems disproportional to the needs of the case. It's also inconsistent with Judge Chen's order that this written discovery should be "limited and focused." 24-1448, ECF No. 84 at 20. Accordingly, the Court limits Defendants' obligation for each RFP to "documents sufficient to show." That seems to get Plaintiffs what they want without overburdening Defendants. Turning again back to RFP 1, it seeks "All Documents referring to written procedures describing the 'storage, handling, sampling, testing, and approval or rejection' of BPO in relation to benzene as a degradant, adulterant, contaminant, or impurity, used in the manufacturing of the Products. *See* 21 CFR § 211.80(a)." The request for "all documents referring to" would capture every single email that mentions the written procedures, which could potentially be a lot of documents. But why do Plaintiffs need them all? What Plaintiffs need are the written procedures themselves (if there are any with respect to benzene) so they can compare them to the cited cGMP to see if there is a straightforward violation. For all of the RFPs, it makes sense to limit them to "documents sufficient to show."

For similar reasons, all of the interrogatories seek relevant and proportional information. In 24-1448, the Defendant answered rogs 3, 4, 9, 10 and 12. In 24-2066, the Defendants answered rogs 1-4 and 8-12. The parties' joint discovery letter briefs do not discuss the adequacy or inadequacy of those responses, so the Court does not reach the issue. Defendants must in the first instance examine their existing responses to see if they comply with the reasoning in this order, and if the responses do not comply, they must amend them. If the parties disagree on whether the existing responses comply with this order, they shall file one or more joint discovery letter briefs.

As for the requests for admission, it looks like Defendants have answered RFAs 1, 2, 12 and 13, so the Court addresses the remainder. They too seek relevant information pertaining to whether Defendants have violated the cGMPs in a manner that requires no interpretation. It's no

response for Defendants to argue the merits of the case.

Accordingly, the Court **GRANTS** Plaintiffs' motions to compel, with the caveats that Defendants need only produce documents "sufficient to show" in response to the RFPs, and that the Court expresses no opinion on the sufficiency of any of the existing rog responses.

IT IS SO ORDERED.

Dated: November 25, 2025

THOMAS S. HIXSON
United States Magistrate Judge